

**CENTER FOR DRUG EVALUATION AND RESEARCH  
(CDER)  
FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Meeting – May 27, and May 28, 2009  
Risk Evaluation and Mitigation Strategies for Certain Opioids  
Hilton Washington D.C./Gaithersburg Hotel  
620 Perry Parkway  
Gaithersburg, MD 20877**

***AGENDA FOR MAY 27, 2009***

**8:30 a.m. – 8:40 a.m.**

**Douglas C. Throckmorton, MD**  
Deputy Director, CDER

Opening Remarks  
Introduction of Panel Members

**8:40 a.m. – 8:45 a.m.**

**Terry Toigo, RPh, MBA**  
Director, Office of Special Health Issues

Logistics

**8:45 a.m. – 10:05 a.m.**

**Mark S. Maginn, MSW, ACSW**  
Pain Advocate

**Carolyn Noel**  
Pain Patient and Advocate

**Mary Vargas, JD**  
Pain Patient and Advocate

**Teresa Shaffer**  
Pain Patient and Advocate

**Leona Nuss**  
Patient Advocate

**Betts Tully**  
Patient Advocate

**Micke A. Brown, BSN, RN**  
Director of Communications/American Pain Foundation  
Past President/American Society for Pain Management Nursing

**Joanne Peterson**

Founder and Executive Director of Learn to Cope

**Joel Simon Hochman, MD**

Executive Director, The National Foundation for the Treatment of Pain

**10:05 a.m. – 10:20 a.m.**

**BREAK**

**10:20 a.m. -- 11:40 a.m.**

**Nicole Kelly**

President, American Chronic Pain Association Board of Directors

**Gregory Terman, MD, PhD**

Associate Professor

Department of Anesthesiology and Pain Medicine

University of Washington School of Medicine

Seattle, Washington

Representing the American Pain Society

**Mark Rasmussen**

President/CEO, National Pain Foundation

**Ed Bisch**

Founder, Oxyabusekills.com

Advocates for Prescription Opioid Drug Reform Member

**Larry Golbom, RPh, MBA**

Host, Prescription Addiction Radio Show – Breaking the Silence

Sponsor of Petition to Ban OxyContin

**Peter W. Jackson**

Bereaved Parent

Advocates for Prescription Opioid Drug Reform

**Sandra Kresser**

Bereaved Parent/Advocate

**Ed Vanicky**

Patient Advocate

**Kirk W. Van Rooyan, MD**

Advocates for Prescription Opioid Drug Reform

**Art Van Zee, MD**

Stone Mountain Health Services  
St. Charles Clinic

**11:40 a.m. – 12:25 p.m.**

**Fred Wells Brason II, Chaplain**

Project Director, Chronic Pain Initiative, Project Lazarus  
Northwest Community Care Network  
Community Health Liaison  
Chair, Substance Abuse Task Force  
Wilkes Healthy Carolinians Council

**Sydney Dy, MD, MSc**

Associate Professor  
Physician Leader, Duffey Pain and Palliative Care Program  
Johns Hopkins Kimmel Cancer Center

**Diana Davis, RN, MSN**

Clinical Services Manager  
Community Hospices of DC, MD, VA

**Valerie Martin, RN**

Director Care Provider to Hospice Patients  
Community Hospices of DC, MD, VA

**Steven Hayes, JD**

Director of Novus Medical Detox Center

**Robert G. Newman, MD, MPH**

Director, Baron Edmond de Rothschild Chemical Dependency Institute,  
Beth Israel Medical Center

**12:25 p.m. – 1:25 p.m.**

**LUNCH**

**1:25 p.m. – 1:50 p.m.**

**Roger Pinsonneault, RPh**

Senior Director, Project Management  
RelayHealth

**Joel S. Policzer, MD, FAAHPM**  
Senior Vice President, National Medical Director  
VITAS Innovative Hospice Care/Palliative Care Solutions

**Nathan Thompson, RPh, MBA**  
Director, Johns Hopkins Outpatient Pharmacies

**1:50 p.m. – 2:15 p.m.**

**Leslie Greenberg, RN, MSN, OCN**  
Health Policy Manager, Oncology Nursing Society

**Karen S. Kaiser, PhD, RN-BC, CHPN, AOCN**  
Oncology Nursing Society

**Chris J. Kottenstette, PA-C**  
Founder & President, PAs in Pain Medicine – a Special Interest Group of the American Academy of Physician Assistants  
Board Member, Colorado Pain Initiative

**2:15 p.m. – 3:15 p.m.**

**Marcie Bough, PharmD**  
Director, Federal Regulatory Affairs  
American Pharmacists Association

**Tracy Baroni Allmon, RPh, JD**  
Vice President, Public Policy  
CVS Caremark

**Stephen Heidenthal**  
Director, Pharmacy Operations  
CVS Caremark

**Thomas R. Clark, RPh, MHS, CGP**  
Director of Clinical Affairs  
American Society of Consultant Pharmacists

**Kevin N. Nicholson, RPh, JD**  
Vice President, Government Affairs and Pharmacy Advisory  
National Association of Chain Drug Stores

**Ronna B. Hauser, PharmD**  
Vice President, Policy and Regulatory Affairs  
National Community Pharmacists Association

**Anita T. Ducca, MS**  
Senior Director, Regulatory Affairs  
Healthcare Distribution Management Association

**3:15 p.m. – 3:30 p.m.**  
**BREAK**

**3:30 p.m. – 3:55 p.m.**

**Nabarun Dasgupta, MPH**  
Researcher  
The RADARS System and the University of North Carolina School of Public Health

**Elise Bailey, MSPH**  
RADARS System Operations/Business Manager  
Denver Health and Hospital Authority

**Edward Sellers, MD, PhD, FRCPC, FACP**  
Vice President, Kendle Early Stage  
Professor Emeritus, University of Toronto

**3:55 p.m. – 4:50 p.m.**  
**Open Public Comment**

**4:50 p.m. – 5:00 p.m.**  
**John K. Jenkins, M.D.**  
Director, Office of New Drugs

Closing Remarks

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***AGENDA FOR MAY 28, 2009***

**8:30 a.m. – 8:40 a.m.**

**Douglas C. Throckmorton, MD**  
Deputy Director, CDER

Opening Remarks  
Introduction of Panel Members

**8:40 a.m. – 8:45 a.m.**

**Terry Toigo, RPh, MBA**  
Director, Office of Special Health Issues

Logistics

**8:45 a.m. – 9:25 a.m.**

**Industry Wide Group Perspective on Class REMS**

**Eric Carter, MD, PhD**  
Chief Science Officer  
King Pharmaceuticals

**Craig Landau, MD**  
Chief Medical Officer  
Purdue Pharma

**Martin A. Lessem, JD**  
Senior Regulatory Associate  
Ranbaxy Laboratories, Inc.

**9:25 a.m. – 9:40 a.m.**

**Elizabeth Ernst**  
Director of Medical and Regulatory Affairs  
Roxane Laboratories

**Kimberly France, RP**

Director, Product and Patient Safety  
Covidien

**9:40 a.m. – 10:05 a.m.**

**Baruch Krauss, MD, EdM, FAAP, FACEP**

Associate Professor of Pediatrics  
Harvard Medical School  
Senior Associate Physician in Medicine  
Children Hospital Boston

**Simon Budman, PhD**

President and CEO  
Inflexxion, Inc.

**Kevin L. Zacharoff, MD**

Director of Medical Affairs,  
Inflexxion, Inc.

**10:05 a.m. – 10:20 a.m.**

**BREAK**

**10:20 a.m. – 12:00 p.m.**

**Ronald W. Buzzeo, RPh**

Chief Compliance Officer  
Cegedim Dendrite

**B. Eliot Cole, MD, MPA, CPE**

Executive Director  
American Society of Pain Educators

**Suzanne R. Eastman, MS, RPh**

Executive Director Clinical Services  
Catalina Health Resource

**Frank Gallo**

Vice President, General Manager  
Rienzi & Rienzi Communications

**Jeffrey Fetterman**

President  
ParagonRx

**John Glover, DPA**

President

John Glover Consulting, Inc.

**Jim Hussey**

CEO

NanoGuardian

**Ravi Harapanhalli, PhD**

Principal Consultant and Late Stage Services Lead

PAREXEL Consulting

**John Harden, MBA**

Certified Security Consultant

Technology Management

**Jack E. Henningfield, PhD**

Professor, Behavioral Biology

The Johns Hopkins University School of Medicine

Vice President, Research and Health Policy

Pinney Associates

**E. Douglas Kramer, MD**

Physician

**Jane C. Maxwell, PhD**

Senior Research Scientist

Addiction Research Institute, The University of Texas at Austin

**12:00 p.m. – 1:00 p.m.**

**LUNCH**

**1:00 p.m. – 1:25 p.m.**

**Sidney H. Schnoll, MD, PhD**

Vice President, Pharmaceutical Risk Management

Pinney Associates, Inc.

Clinical Professor of Internal Medicine and Psychiatry

Virginia Commonwealth University

**Kathleen S. Strauser, BS, MBA**

Executive Vice President

MediCom Education Group

**Jennifer Bolen, JD**

Attorney at Law

Founder of the Legal Side of Pain and the Pain Law Institute

**1:25 p.m. – 2:25 p.m.**

**Karla Stricker Anderson**

Managing Director, Life Sciences Commercial Operations

BearingPoint

**Dewey Seto**

Manager, Life Sciences Commercial Operations

BearingPoint

**Richard Slattery**

REMS Solution Team

President, Clinical Marketing Consortium

**Stephen Porada**

REMS Solution Team

Aventine HealthSciences

**Phillip D'Alessandro**

President & CEO

YNF, LLC

**Edgar H. Adams, ScD**

Executive Director, Epidemiology

Covance Inc.

**Thomas Noto**

Vice President, Regulatory Affairs and Quality Assurance

Covance Periapproval Services

Covance Inc.

**2:55 p.m. – 3:15 p.m.**

**BREAK**

**3:15 p.m. – 3:55 p.m.**

**Ardis D. Hoven, MD**

American Medical Association Trustee

**John G. Carney**

Vice President, Aging and End of Life

Center for Practical Bioethics

**Marti Hottenstein**

Vice President

HARMD Inc.

**Melissa Zuppari**

President

HARMD Inc.

**Lenore Duensing, MEd**

Executive Director

American Academy of Pain Management

**3:55 p.m. – 4:50 p.m.**

**Open Public Comment**

**4:50 p.m. – 5:00 p.m.**

**John K. Jenkins, M.D.**

Director, Office of New Drugs

Closing Remarks